

## **REMARKS**

Applicant thanks the Office for its conscientious prosecution of this application. Applicant has carefully studied the non-final Examiner's Action mailed November 16, 2007 along with the references cited therein. The following explanatory remarks are believed to be fully responsive to the Action. Accordingly, this important patent application is now believed to be in condition for allowance.

### ***Claim Rejections - 35 U.S.C. § 112, second paragraph***

Claims 17 and 18 stand rejected under 35 U.S.C. § 112, second paragraph, for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the Office points out the ambiguity relating to the language "wherein the compound has a concentration between about 1.0 uM and about 10.0 uM of imatinib mesylate and suberoylanilide hydroxamic acid." Applicant has amended the claims to remove the ambiguity.

### ***Claim Rejections - 35 U.S.C. § 103***

Claims 17 - 25 stand rejected under 35 U.S.C. §103(a) as being unpatentable over *Van Emelen et al.* (U.S. Patent Application Publication No. U.S. 2005/0096468) in view of *Jolivet et al.* (U.S. Patent No. 6,645,972). Applicant respectfully traverses the rejection, however, on the grounds that neither reference qualifies as prior art.

As a preliminary matter, the Office has stated (in response to Applicant's previous comments that *Van Emelen et al.* is only entitled to the PCT filing date under 35 U.S.C. §102(e)) that:

35 U.S.C. §102(e) is explicitly limited to certain references "filed in the United States before the invention thereof by the applicant" [(Emphasis added)]. The PCT filed by Van Emelen et al. was filed in Europe.<sup>1</sup>

Applicant interprets these statements as indicating that *Van Emelen et al.* was not cited as prior art under 35 U.S.C. §102(e). A 35 U.S.C. §103 rejection is based on 35 U.S.C. §102(a), 102(b),

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<sup>1</sup> Non-Final Office Action, mailed November 16, 2007, page 6.

102(e), etc. depending on the type of prior art reference used and its publication or issue date.<sup>2</sup> U.S. patent application publications are prior art under 35 U.S.C. §102(a) and 102(b) as of the publication date.<sup>3</sup> Only under 35 U.S.C. §102(e)(1) is a published patent application to be considered prior art as of the earliest effective U.S. filing date of the published application.<sup>4</sup>

35 U.S.C. §102(e) states that “an international application filed under the treaty defined in section 351(a) shall have the effects for the purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.” Here, the PCT application designated the United States and was published under Article 21(2). Therefore, Applicant respectfully submits that *Van Emelen et al.* has been cited as a §102(e) reference.

Turning now to the substance of the rejection, *Van Emelen et al.* (2005)<sup>5</sup> is a U.S. Patent Application Publication with a publication date of May 5, 2005 and a PCT filing date of March 11, 2003. The intervening international publication, *Van Emelen et al.* (2003)<sup>6</sup>, published September 18, 2003. The Office, however, relies on the provisional application date for *Van Emelen et al.* (2002)<sup>7</sup>, March 13, 2002, as the critical reference date. To qualify as a reference under §102(e) the subject matter used in the rejection must be disclosed in the underlying provisional application in compliance with 35 U.S.C. §112, first paragraph.<sup>8</sup>

In rejecting the claims, the Office points to *Van Emelen et al.* (2005). Specifically, on page three (3) of the Office Action, it is alleged that *Van Emelen et al.* (2005) teaches a combination of a Histone Deacetylase (HDAC) inhibitor (page 6, para. [0084]) and another agent to treat cancer and cause apoptosis of cancer cells, including leukemias (page 6, para. [0085] – [0086]). The Office further interprets *Van Emelen et al.* (2005) to teach the use of agents such as kinase inhibitors (specifically imatinib mesylate) (page 8, para. [0128]) and HDAC inhibitors such as suberoylanilide hydroxamic acid (SAHA) (page1, para. [0004] and page 8, para. [0149]). While

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<sup>2</sup> MPEP §2141.01

<sup>3</sup> MPEP §901.03

<sup>4</sup> MPEP §903.03, §706.02(f) et. seq.

<sup>5</sup> U.S. Patent Application Publication No. 2005/0096468 to *Van Emelen et al.*, filed March 11, 2003, published May 5, 2005.

<sup>6</sup> International Publication No. WO 03/075929, filed March 11, 2003 and published September 18, 2003.

<sup>7</sup> U.S. Provisional Application No. 60/363,799, to *Van Emelen et al.*, filed March 13, 2002.

<sup>8</sup> MPEP §706.02(f)(1)

Applicant respectfully disagrees with this interpretation, the teachings of *Van Emelen et al.* (2005) are moot as it does not qualify as prior art.

*Van Emelen et al.* (2002) consists of a markedly different specification than that of *Van Emelen et al.* (2005). In fact, *Van Emelen et al.* (2002) is silent as to the combination of the disclosed HDAC inhibitor (which is not SAHA) with a tyrosine kinase inhibitor of any kind. Although *Van Emelen et al.* (2002) discloses other hydroxamic acids of the new compound<sup>9</sup>, it is silent as to the use of SAHA in combination with the disclosed compound. *Van Emelen et al.* (2002) does teach that the disclosed compound can be used with “one or more other medical agents such as anti-cancer agents”<sup>10</sup> but does not include any tyrosine kinase inhibitor or SAHA as such an agent. *Van Emelen et al.* (2002) does not contain, either expressly or inherently, the material relied upon in the rejection in compliance with 35 U.S.C. §112, first paragraph. Therefore, the filing date of *Van Emelen et al.* (2002) cannot be extended to *Van Emelen et al.* (2005).

The date of priority for this application is September 19, 2002. *Van Emelen et al.* (2003) and *Van Emelen et al.* (2005) are effective as references only as of March 11, 2003 (the PCT filing date) under 35 U.S.C. §102(e). The effective reference date does not predate Applicant’s priority date and therefore *Van Emelen et al.* does not qualify as prior art.

The underlying provisional application of *Jolivet* is similarly flawed. Applicant, however, forgoes discussion of *Jolivet* as its teachings are moot in light of unavailability of *Van Emelen et al.* as prior art.

### ***Conclusion***

Entry of a Notice of Allowance is solicited. If the Office is not fully persuaded as to the merits of Applicant's position, or if an Examiner's Amendment would place the pending claims in condition for allowance, a telephone call to the undersigned at (813) 925-8505 is requested.

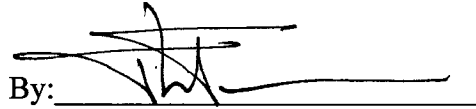
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<sup>9</sup> *Van Emelen et al.* (2002), page 5, para. [0078].

<sup>10</sup> *Van Emelen et al.* (2002), page 16, line 30 through page 17, line 7.

Very respectfully,

SMITH & HOPEN

By: 

Dated: May 16, 2008

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**(37 C.F.R. 2.190 (b))**

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Date: May 16, 2008

/jessica powell/

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Jessica Powell